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Philips Medical Systems (Cleveland) Inc.

510(k) Summary

Philips IMR Software Application

JUN 7 2013

The summary of this 510(k) provides safety and effectiveness information submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter:

   Philips Medical Systems (Cleveland), Inc.
   595 Miner Road
   Cleveland, OH 44143

   Contact:

   Christine Anderson
   Regulatory Affairs Specialist
   Tel.: (440) 483-7732
   Fax: (440) 483-4918

   Date of Summary: November 16, 2012

2. Device Name and Classification

Device Name:	Philips IMR Software Application
Device Classification:	Computed Tomography X-Ray System. The FDA has classified the Computed Tomography X-Ray System and its accessories as Class II in 21 CFR 892.1750 (Product Code: 90 JAK)

3. Predicate Device Information

   The Philips IMR Software Application is comparable in type and substantial equivalence to the legally marketed devices currently in commercial distribution, namely:
   a. Philips IRT Software Application – K113483
   b. Philips Brilliance Volume CT System – K060937

4. Device Description

   The IMR reconstruction feature is intended as an alternative to standard reconstruction methods (filtered back projection) for the reconstruction of CT scanner data to produce diagnostic images. The IMR reconstruction feature is designed to reduce image noise, increase high-contrast spatial resolution, and improve low contrast detectability. IMR is designed to reduce dose required for diagnostic CT imaging. Image quality improvements and dose reduction depend on the clinical task, patient size, anatomical location, and clinical practice. The

IMR Software Application will reside on any Philips CT System that meets minimum software platform and hardware requirements. IMR enables the user to apply iterative reconstruction techniques to reconstruct raw CT data to generate diagnostic CT images. The use of IMR to reconstruct images may be done prospectively or retrospectively.

5. Indications for Use

The IMR reconstruction feature is intended as an alternative to standard reconstruction methods (filtered backprojection) for the reconstruction of CT scanner data to produce diagnostic images. The IMR reconstruction feature is designed to reduce image noise, increase high-contrast spatial resolution, and improve low contrast detectability. IMR is designed to reduce dose required for diagnostic CT imaging. Image quality improvements and dose reduction depend on the clinical task, patient size, anatomical location, and clinical practice. IMR images will be used by a trained medical professional for diagnosis of clinical conditions in patients, including pediatrics and adults, who have been prescribed a CT scan as part of their clinical care.

6. Comparison to Predicate

In the opinion of Philips, the IMR Software Application is of a comparable type and substantially equivalent to the Philips Brilliance Volume CT System and the IRT Software Application, the legally marketed devices described in section 3 above. IRT reconstructs images from raw data based on iterative processing using the raw and image data. IMR is identical to IRT except for additional use cases and additional claims for image quality, as measured on a phantom, and dose reduction claims, as evaluated via a human observer study. Therefore, IMR expands on the capabilities of IRT.

Predicate	510(k) Number	Cleared
Brilliance Volume	K060937	June 5, 2006
Philips IRT Software Application	K113483	September 26, 2012

7. Safety

The Philips IMR software application is manufactured in accordance with the Quality System Regulation (QSR) 21 CFR 820 and to International Standards ISO 13485:2003. Potential hazards are identified in a hazard analysis and controlled in the following manner:

Software: Safety is assured by the company procedures that conform to accepted practices, including the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

Instructions for Use are provided with the software application for the safe and effective operation of the application by the user.

8. Performance Testing Summary

Non-clinical Testing

Objective image quality testing was conducted using phantoms and following the methodology in IEC 61223-3-5, Evaluation and routine testing in medical departments – Parts 3-5: Acceptance test – Imaging performance of computed tomography x-ray equipment for determining noise, CT number, CT number uniformity and high contrast spatial resolution. The CT scan data was reconstructed both with filtered backprojection and the IMR software application for comparison. Additionally, a Four Alternative Force Choice (4-AFC) Detection human observer study was conducted with a four Low Contrast pin phantom for evaluating low contrast detectability (LCD). In this study, a cohort of human subjects was required to identify a low contrast pin in a panel of four images. In order to characterize the statistical nature of the detection of a low contrast object in an image with noise, the test was repeated multiple times for each test subject, and multiple test subjects were used. The resulting data confirmed the improved LCD using the IMR application.

IMR may simultaneously enable 60% – 80% lower radiation dose; and 43% – 80% low-contrast detectability improvement; and 70% – 83% less image noise, relative to filtered backprojection, as demonstrated through phantom-based tests. Low-contrast detectability was assessed using a reference abdomen protocol, based on a 4-AFC phantom test.

IMR may alternatively enable 1.2x – 1.7x high-contrast spatial-resolution improvement; or 2.5x – 3.6x low-contrast detectability improvement; or up to 90% image noise reduction, relative to filtered backprojection, as demonstrated through phantom-based tests. Lower image noise assessed using a Reference Chest Protocol; Improved high-contrast spatial resolution using Reference Abdomen and Thorax Protocols; Improved low-contrast detectability using a Reference Abdomen Protocol. All metrics tested on phantoms.

Clinical Image Evaluation

A total of 110 clinical image raw data sets were reconstructed with filtered backprojection and then with the IMR software application to compare image quality. The FBP and IMR images were evaluated image quality by a panel of eight physicians. Resulting data confirmed that the IMR software application provides diagnostic quality images and in majority of the cases, the physicians preferred the IMR images to standard (filter back projection) reconstruction.

Conclusion

IMR may simultaneously enable:

- 60% – 80% lower radiation dose; and
- 43% – 80% low-contrast detectability improvement; and
- 70% – 83% less image noise,

relative to filtered backprojection, as demonstrated through phantom-based tests[1].

IMR may alternatively enable:

- 1.2x – 1.7x high-contrast spatial-resolution improvement[2]; or
- 2.5x – 3.6x low-contrast detectability improvement [3]; or
- Up to 90% image noise reduction[4],

relative to filtered backprojection, as demonstrated through phantom-based tests.

Note : In clinical practice, the use of IMR may reduce CT patient dose depending on the clinical task, patient size, anatomical location, and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task.

The table below represents the test conditions used to achieve the above performance parameters

IMR Image Quality Parameter	Results	Test Conditions
Dose Reduction: 60%-80% lower dose with simultaneous improved image quality [1]	60% lower radiation dose with a 43 % improvement in low contrast detectability and 83% less image noise	**Lower (60%) limit as specified by**: IMR settings: • Reference Protocol[1]: Abdomen • $CTDI_{vol}$: 4 mGy • Slice thickness: 0.8/0.4mm • Clinical indication: Sharp • Level: L3 As compared to: FBP settings • Reference Protocol: Abdomen • $CTDI_{vol}$: 10mGy, • Slice thickness: 0.8/0.4 mm, • Standard filter: C As tested on the MITA CT IQ Phantom manufactured by Phantom Laboratories, model CCTI83 and low contrast detectability testing using human observers.

[1] Reference protocols refer to the standard factory reference protocols provided on the CT scanner

	80% lower radiation dose with a 80% improvement in low contrast detectability and 70% less image noise.	**Upper limit (80%) as specified by** IMR settings: • Reference protocol: Abdomen • $CTDI_{vol}$: 2mGy • Slice thickness: 0.8/0.4mm • Clinical indication: Smooth • Level: L3 As compared to: FBP settings • Reference Protocol: Abdomen • $CTDI_{vol}$: 10mGy • Slice thickness: 0.8/0.4 mm, • Standard filter: B As tested on the MITA CT IQ Phantom manufactured by Phantom Laboratories, model CCTI83 and low contrast detectability testing using human observers.

High-contrast spatial resolution improvement [2]	1.2x – 1.7x high-contrast spatial-resolution improvement	High-contrast spatial resolution (x-y) and image noise. **Lower limit as specified by:** IMR settings • Reference Protocol: Abdomen • $CTDI_{vol}$: 4mGy • Slice thickness:1.0/0.5 mm • Clinical Indication: Sharp • Level: L3. As compared to: FBP Settings • Reference Protocol: Abdomen • $CTDI_{vol}$: 4mGy • Slice thickness: 1.0/0.5 mm, • Standard filter: B **Upper limit as specified by**: IMR settings • Reference Protocol: Thorax/High Res Helical Protocol • $CTDI_{vol}$: 20mGy • Slice thickness: 1.0/0.5 mm • Matrix: 512 matrix • Clinical Indication: Sharp • Level: L3 As compared to: FBP Settings • Reference Protocol: Abdomen • $CTDI_{vol}$: 20mGy • Slice thickness:1.0/0.5 mm, • Standard filter: B Tested on the CatPhan 600.

Low-contrast detectability improvement [3]	2.5x – 3.6x low-contrast detectability improvement	**Lower limit as specified by:** IMR Settings: • Reference Protocol: Abdomen • $CTDI_{vol}$:10 mGy • Slice thickness: 0.8/0.4 mm, • Clinical Indication: Sharp • Level: L3 As compared to: FBP Settings • Reference Protocol: Abdomen • $CTDI_{vol}$: 10mGy • Slice thickness: 0.8/0.4 mm, • Standard filter: C **Upper limit as specified by:** IMR Settings: • Reference Protocol: Abdomen • $CTDI_{vol}$: 4 mGy • Slice thickness: 0.8/0.4 mm, • Clinical Indication: Smooth • Level:L3 As compared to: FBP Settings • Reference Protocol: Abdomen • $CTDI_{vol}$: 4mGy • Slice thickness: 0.8/0.4 mm, Standard filter: B As tested on the MITA CT IQ Phantom manufactured by Phantom Laboratories, model CCTI83 and low contrast detectability testing using human observers
Noise reduction [4]	90% image noise reduction	IMR Settings: • Reference Protocol: Chest • $CTDI_{vol}$: 20 mGy • Slice thickness: 0.8/0.4 mm, • Clinical Indication: Smooth • Level: L3 As compared to: FBP Settings: • Reference Protocol: Chest • $CTDI_{vol}$: 20mGy • Slice thickness: 0.67/0.34 mm, • Standard filter: B Tested on the CatPhan 600 with cylindrical body ring.

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Based on the above considerations, it is Philips' opinion that the results of the verification and validation testing and the results of the risk analysis demonstrates safety and effectiveness of the Philips IMR Software Application and that it is substantially equivalent to the predicate devices documented above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 7, 2013

Philips Medical System (Cleveland) Inc.
% Ms. Christine Anderson
Regulatory Affairs Specialist
595 Miner Road
CLEVELAND OH 44143

Re: K123576
Trade/Device Name: IMR Software Application
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: May 31, 2013
Received: June 04, 2013

Dear Ms. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of in vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123576

Device Name: IMR Software Application

Indications for Use:

The IMR reconstruction feature is intended as an alternative to standard reconstruction methods (filtered back projection) for the reconstruction of CT scanner data to produce diagnostic images. The IMR reconstruction feature is designed to reduce image noise, increase high-contrast spatial resolution, and improve low contrast detectability. IMR is designed to reduce dose required for diagnostic CT imaging. Image quality improvements and dose reduction depend on the clinical task, patient size, anatomical location, and clinical practice. IMR images will be used by a trained medical professional for diagnosis of clinical conditions in patients, including pediatrics and adults, who have been prescribed a CT scan as part of their clinical care

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

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